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(54) Multi-rule quality control method and apparatus

(57) A method and apparatus for analyzing the results of determinations of the concentrations of medically significant components of control solutions comprise providing a programmable machine, executing on the machine a program which tests the results against a set of statistical quality control rules, and producing indications to an operator of the results of the tests. Illustratively, (a) laboratory analytical instrument(s) run(s) the control solutions interspersed among patient samples, the concentrations of medically significant components of which are determined by the laboratory instrument(s). The quality of the laboratory instrument's(s) process(es) for determining the concentrations of the medically significant components of the patient samples are monitored by testing the outcomes of the concentration determinations of the control solutions against the set of QC rules. The QC testing process is conducted as the concentrations of the medically significant components of the control solutions are determined, so that delays between the determination of the concentrations of the medically significant components of the patient samples and the determination of the state of control of the process(es) by which those concentrations are determined are minimized.

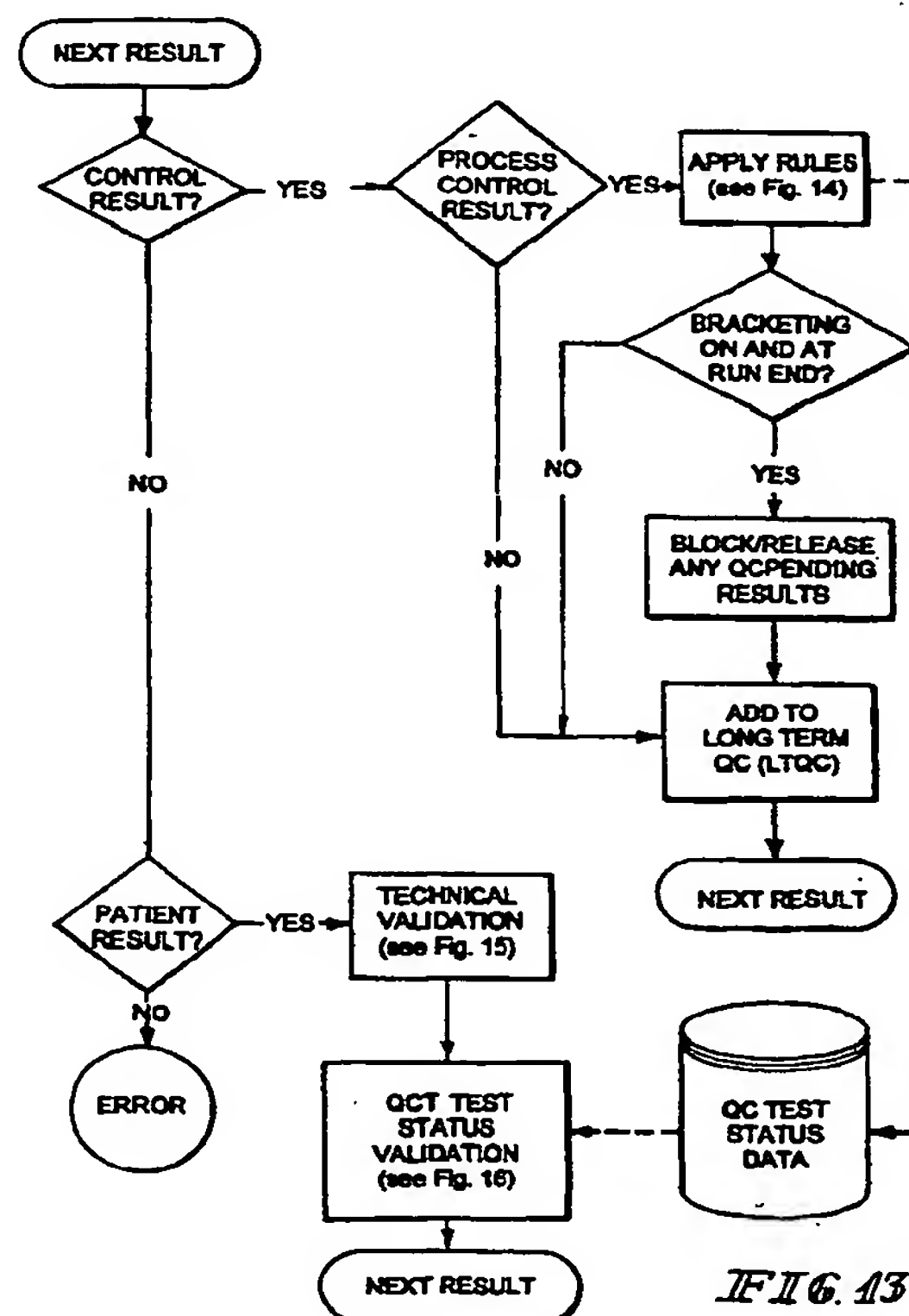


FIG. 13

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### Description

## Field of the Invention

5 **[0001]** This invention relates to laboratory information management systems of the type wherein one or more automated or partly automated laboratory instruments, for example, instruments for determining the concentrations of medically significant components of samples of body fluids and/or tissues from patients who have submitted such samples for testing, provide information such as identifying indicia and control solution test results to a programmable machine which is programmed to test such results against statistical quality control criteria defined by way of rules.

### Description of the Background Art

15 **[0002]** Laboratory information management systems are known generally. Some such systems permit the operator to select a rule against which one or a group of such results may be tested. Typically, the way in which this is done is that control solutions having known concentrations of a medically significant component of interest, for example, a hormone, are processed by the laboratory instrument right along with patient samples. The programmable machine then tests the laboratory instrument's concentration determination results against the known concentrations of the hormone in the various controls as determined by the laboratory instrument.

**[0003]** The statistical quality control test, or rule, might be, for example, "Is the reported result for the control solution within one standard deviation of the known concentration?" If the answer to such a test is "Yes," the laboratory instrument's concentration determination process is considered to be in control, and testing to determine the concentration of the hormone in patient samples proceeds. If the answer to this question is "No," the laboratory instrument's concentration determination process is considered to be out of control, and appropriate steps are taken to bring the process back into control and/or to retest the affected patient sample concentration determinations to provide more reliable results.

**[0004]** There are various sources of statistical quality control rules. Examples of collections of such rules are the so-called Rilibak rules and the Westgard rules, attributed to Dr. James O. Westgard. Westgard statistical quality control has been implemented manually in the control of processes using Shewhart charts. These statistical quality control strategies, while effective, permitted only off-line, non-real time testing of process results against the statistical quality control rules. What this ordinarily meant in the manufacturing context, for example, is that by the time statisticians became aware that a manufacturing process was out of control, several potentially non-conforming units of manufacture had already been produced. This, of course, typically dictated that further quality checking be performed on suspected non-conforming units of manufacture, and/or corrective action be taken as necessary.

### 35 Disclosure of the Invention

**[0005]** According to an aspect of the invention, a system for analyzing the results of determinations of the concentrations of medically significant components of control solutions comprises a programmable machine, and a program executable on the machine for testing the results against a set of multiple rules and for producing indications to an operator of the results of the tests.

**[0006]** Illustratively according to this aspect of the invention, the system further comprises an instrument for sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions, and an interface for relaying the results of the determinations of the concentrations of the medically significant components of the control solutions to the programmable machine to be tested by the program.

45 **[0007]** Further illustratively according to this aspect of the invention, the program for testing the results against multiple rules comprises a program for testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules, and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second  
50 subset of the set of multiple rules.

**[0008]** Additionally illustratively according to this aspect of the invention, the instrument for sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions comprises an instrument for sequentially determining the concentrations of different medically significant components of samples of different body fluids and different control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and different control solutions, and the program comprises a program for instructing the instrument to determine the concentrations of different medically significant components of samples of different body fluids and different control solutions, and the system further comprises an interface for relaying instructions from the programmable machine to the instrument.

[0009] Additionally according to this aspect of the invention, the system further comprises a second instrument for sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions, and an interface for relaying the results of determinations by the second instrument to the programmable machine to be tested by the program.

5 [0010] Further illustratively according to this aspect of the invention, the instrument and the second instrument respectively comprise: an instrument for sequentially determining the concentrations of different medically significant components of samples of different body fluids and control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and control solutions; and, a second instrument for sequentially determining the concentrations of different medically significant components of samples of different body fluids and control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and control solutions, and the program comprises a program for selectively instructing one of the instrument and the second instrument to determine the concentrations of different medically significant components of samples of different body fluids and control solutions, the system further comprising an interface for relaying instructions from the programmable machine to the one of the instrument and the second instrument.

15 [0011] According to another aspect of the invention, a method for analyzing the results of determinations of the concentrations of medically significant components of control solutions comprises the steps of providing a programmable machine, testing the results on the machine against a set of multiple rules, and producing indications to an operator of the results of the tests.

20 [0012] Illustratively according to this aspect of the invention, the method further comprises the step of sequentially determining the concentrations of medically significant components of multiple samples of control solutions and body fluids, and relaying the results of the determinations of the concentrations of the medically significant components of the control solutions to the programmable machine to be tested by the program.

25 [0013] Additionally according to this aspect of the invention, testing the results against multiple rules comprises testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.

30 [0014] Further according to this aspect of the invention, sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions comprises sequentially determining the concentrations of different medically significant components of samples of different body fluids and control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and control solutions, instructing the determination of the concentrations of different medically significant components of samples of different body fluids and control solutions, and relaying instructions from the programmable machine to the instrument.

35 [0015] Additionally illustratively according to this aspect of the invention, testing the results against the set of multiple rules comprises testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.

#### Brief Descriptions of Illustrative Drawings

45 [0016] The invention may best be understood by referring to the following detailed description and accompanying drawings which illustrate the invention. In the drawings:

Figs. 1-12 illustrate certain screens generated by an apparatus and method according to the present invention; and,

50 Figs. 13-16 illustrate flow diagrams of program modules for conducting a method according to the present invention on an apparatus according to the present invention.

#### Detailed Descriptions of Specific Embodiments

55 [0017] Multi-rule statistical quality control strategies employ combinations of rules to achieve lower incidences of false rejects for the same probability of detecting a given size error than single rule statistical quality control strategies can. The rules employed in implementing such strategies can include, for example, combinations of two or more of the following rules. In the following rules, "ks," where k is an integer, means k standard deviations; "W" means within a run;

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according to the invention also support the bracketing mode. As previously noted, in the bracketing mode, patient results are held until results of the testing of one or more controls by the instrument are evaluated by the multi-rule strategy. Once the results of the instrument's testing of the control(s) is(are) tested against the suite of rules and the instrument is determined from this testing to be in control both before and after the patient sample(s) was(were) evaluated, the patient results are released, for example, to a patient results data base.

**[0020]** The system of the present invention provides: a method for selecting and configuring the suite of QC rules against which a particular result or group of results will be tested; an engine that evaluates results as they arrive at the programmable machine; a display of whether the measurement process is in control according to each selected rule of the suite, or whether the measurement process is under caution according to that rule, or whether the measurement process is out of control according to that rule; a means for the operator to set the status of a particular result or group of results with respect to selected criteria independent of rule status--for example, an operator can overwrite the selected rule(s) and always be in control of the process; a visual indication of the condition of statistical quality control testing of the results against each rule--for example, "green" = ok, "yellow" = warning, and "red" = failed when tested against a particular rule; a display of the state of a particular result or group of results with respect to a particular rule; automatic switching of the state of a particular result or group of results when testing of the control(s) associated with that particular result or group of results against a rule indicates that the process by which the result(s) is(are) obtained is or may be out of control; automatic release of validated results generated by the laboratory instrument, for example, into a data base of such results, as long as testing of the control(s) associated with that particular result or group of results against all selected rules indicates that the process by which the result(s) is(are) obtained is in control; when the testing is being conducted in bracketing mode, automatic switching of the state of a particular result or group of results when testing the controls associated with that particular result or group of results against all selected rules indicates that the process by which the result(s) is(are) obtained is in or out of control, respectively, and automatic passage of that(those) result(s) to the data base, or withholding of that (those) result(s) from the data base, respectively, depending upon the state of that particular result or group of results.

**[0021]** The multi-rule quality control testing method and apparatus can be integrated into laboratory system data handling and management software. In the illustrated example, the multi-rule process and apparatus are implemented as components of the LSM, the disclosure of which is incorporated herein by reference. In the LSM, information, prompts, etc., are displayed to the operator on screens designed to resemble hanging file folders. The tabs at the tops of the various folders select those folders. Selection of one of the folders causes that screen, its contents, menu, etc., to be displayed to the operator. The screens which are accessed by the multi-rule method and apparatus in the illustrated embodiment include a test status screen which displays the status, for example, in control (indicated by a green circle), caution (indicated by a yellow circle containing an exclamation mark), and out of control (indicated by a red circle containing an "X"). In the illustrated embodiment, the test status screen also displays a list of outstanding quality control violations produced by rule failures, and details of the control results associated with each failure. From this screen, an operator can also manually control the status of a test and view a log of all manual operator QC events and interactions. Any comments added by operators in connection with manual operator QC events and interactions can also be viewed and edited. These comments will indicate by which operator and when the comments were entered, protecting against someone else changing the comment, but permitting adding to the comment. A library of standard comments is also available from which the user can select (a) standard comment(s). Illustrative test status screens are illustrated in Figs. 1-4. An illustrative test status report is illustrated in Table 1.

Table 1

Test		Instrument	Test State	WITHIN RUN										ACROSS RUN										ACROSS SYSTEM	
				102s		R0Ks		302s		401s		Mxbar		202s		20302s		401s		Mxbar					
				wC		wC	aC	wC	aC	wC	aC	wC	aC	wC	aC	wC	aC	wC	aC	wC	aC				
CkMb		ELEC1	0		0	0					0														
Calcium		ES001	X	1						X					0										N
Creatinin		ES002	0		0	0									0										

0 = OK, 1 = Warning, X = Error, I = Incomplete

Last Control Results (for user-selected interval): (This table is printed only if Last Results were requested)

Test	Instrument	Control	Result	SDI	Target	SD	Date	Time
CKMb	ELEC1	PPIM	91.3	1.3	81.4	10.3	1/10/96	12:29 PM
		PNIM	28.4	1.9	20.6	4.7	1/8/96	9:08 AM
Calcium	ES001	PPIM	91.3	1.3	81.4	10.3	1/10/96	12:29 PM
		PNIM	28.4	1.9	20.6	4.7	1/8/96	9:08 AM
		CPID	43.3	-0.4	44.0	1.7	1/9/96	10:27 AM
Creatinin	ES001	PPIM	91.3	1.3	81.4	10.3	1/10/96	12:29 PM

Table 1 continued

QC Event List for CkMb on ELECI (for user-selected interval): (This table is printed only if Events were requested)

Event	Control	Date	Time
Violation: 1 x 3s Rule	PNIM	1/10/96	12:49 PM
Status Green: JONESMT		1/10/96	12:47 PM
Violation: 2 of 3 x 2s Rule	PRIM	1/10/96	12:44 PM
Warning: 4 x 1s Rule	PRIM	1/10/96	12:29 PM
Status Green: JONESMT		1/10/96	11:54 PM
Status Red: RICKDJ		1/10/96	11:10 PM

QC Event List for Calcium on ES001 (for user-selected interval): (This style table is printed if Comments were requested)

Event	Date	Time	Control/Comment
Violation: 1 x 3s Rule	1/10/96	12:49 PM	PNIM Appears to be a false rejection (A violation could have a comment)
Status Green: JONESMT	1/10/96	12:47 PM	Put in the wrong vial
Violation: 2 of 3 x 2s Rule	1/10/96	12:44 PM	PPIM
Warning: 4 x 1s Rule	1/10/96	12:29 PM	PPIM
Status Green: JONESMT	1/10/96	11:54 AM	Recalibrated and got 3 QC's within 1SD after discovering (and removing) spider's web covering sensor (Comments wrap as necessary)
Status Red: RICKDJ	1/10/96	11:10 AM	Getting a lot of bad patient results so I assume something is wrong.

Table 1 continued

QC Event List for Creatinin on ES001 (for user-selected interval): (This style table is printed if Details were requested)									
Event	Date	Time	Control	Result	SDI	Target	SD	Date	Time
Violation: 1 x 3s Rule	1/10/96	12:49 PM	PPIM	91.3	1.3	81.4	10.3	1/10/96	12:29 AM
Status Green: JONESMT	1/10/96	12:47 PM							
Violation: 2 of 3 x 2s Rule	1/10/96	12:44 PM	PPIM	98.3	2.3	81.4	10.3	1/10/96	12:29 AM
			PNIM	28.4	1.9	20.6	4.7	1/8/96	9:08 AM
			PPIM	99.6	2.5	81.4	10.3	1/10/96	12:29 AM

Table 1 continued

QC Event List for Creatinin on ES002 (for user-selected interval): (This style table is printed if Details and Comments were requested)						
Event	Date	Time	Details/Comments			
			Control	Result	SDI	Target SD Date Time
Violation: 1 x 3s Rule	1/10/96	12:49 PM	PPIM	91.3	1.3	81.4 10.3 1/10/96 12:29 AM
			Appears to be a false reject			
Status Green: JONESMT	1/10/96	12:47 PM	Put in the wrong vial			
Violation: 2 of 3x 2s Rule	1/10/96	12:44 PM	PPIM	98.3	2.3	81.4 10.3 1/10/96 12:29 PM
			PNIM	28.4	1.9	20.6 4.7 1/8/96 9:08 AM
			PPIM	99.6	2.5	81.4 10.3 1/10/96 12:29 AM
Warning: 4 x 1s Rule	1/10/96	12:29 PM	PPIM	91.3	1.3	81.4 10.3 1/10/96 12:29 PM
			PNIM	28.4	1.9	20.6 4.7 1/8/96 9:08 AM
			PPIM	91.3	1.3	81.4 10.3 1/10/96 12:29 PM
			PNIM	28.4	1.9	20.6 4.7 1/3/96 9:08 AM
Status Green: JONESMT	1/10/96	11:54 AM	Recalibrated and got 3 QC's within 1SD after discovering (and removing) spider's web covering sensor			
Status Red: RJCKDJ	1/10/96	11:10 AM	Getting a lot of bad patient results so I assume something is wrong			

[0022] The screens also include a multi-rule QC rules administration screen. Using this screen the operator can select the operating mode for a test, for example, whether the test will be performed as an open run or as a bracketed run. This screen permits the operator to select the run length. If the control result(s) being tested is (are) part of an open run,



Table 2

QC Rule Settings				WITHIN RUN												ACROSS RUN												ACROSS SYSTEM					
Test	Instrument	Run Len.	Bracketing	RoKs			2σ2s			4σ1s			Mxbar			2σ2s			4σ1s			Mxbar			RoKs								
				wC	aC	K	wC	aC	K	wC	aC	K	wC	aC	K	wC	aC	K	wC	aC	K	wC	aC	K	wC	aC	K						
CLMB	ELEC1	4																															
Calcium	ES001	6	X	W	W	2.51																											
Creatinine	ES002	5		W																													
Calcium	ES001	5	X																														
IT3	ELEC1	4		E																													
IT4	ELEC1	3																															
Glucose	ES002	3																															
IT3	ELEC1	2																															
IT4	ELEC1	1		E																													
TBK	ES001	3																															
TROPO	ES001	4																															
TSH	ES001	2																															

W = QC Warning rule, E = QC Error rule

[0023] A control definition screen permits the operator to establish quality control-specific parameters of control materials, such as, for example, mean values and standard deviations of the biologically significant components of those controls. This screen also permits designation of a particular lot of material as a process control lot or study lot, A study

lot is a lot which is used in statistical calculations, but not in the multi-rule quality control strategy for controlling the process. Illustrative control definition screens, pages 1 and 2, are illustrated in Figs. 6-7.

[0024] A QC results screen permits the operator to view control results in detail. The operator can exclude or include control results from the long term quality control statistics as well as delete ones which are the result of gross operator errors, such as the misidentification of a material. An illustrative QC results screen is illustrated in Fig. 8.

[0025] A patient validation screen permits functions similar to the QC results screen, but also permits the viewing and disposition of patient results in the context of their associated control results. Illustrative patient validation screens, the first screen and a screen displayed when the "more" button is clicked, are illustrated in Figs. 9-10.

[0026] A comment administration screen permits entry of comments which can then be selected from a menu. A comment dialog is presented to the operator for the entry of text, either to add text to an existing comment or to provide a new comment. The method and apparatus of the present invention will typically be configured to automatically present the dialog whenever the operator performs certain actions such as forcing (a) result(s) into an out of control condition or into an in control condition, excluding (a) control result(s), and so on. This screen is intended to encourage the operator to enter comments to help document and explain such actions. This supports a laboratory policy of encouraging operators to comment by offering an opportunity for them to do so, or enforcing the entry of comments where appropriate. An illustrative comment administration screen is illustrated in Fig. 11.

[0027] A user access rights administration screen permits the system to be tailored to varying levels of access by different operators. For example, some operators may be permitted to access all system screens while others are permitted to access only certain screens. An illustrative user access rights administration screen is illustrated in Fig. 12.

[0028] Two background modules provide most of the internal functions of the multi-rule QC system. One of these, the run module, monitors the receipt of control and patient results from the various laboratory instruments whose results the system is monitoring, passes control results to the other module, a rules evaluation module, and modifies the status of a test according to the evaluation results. After checking patient results for normal ranges, etc., the run module can automatically release a patient result if the corresponding test status is in control and the rule against which the associated control is tested is operating in open run mode. If the rule is operating in bracketing mode, the run module does not release a patient result until the module has received and tested sufficient control results to establish that the entire bracketed run is in control. The run module also provides certain services to the various screens to support operator actions, such as forcing a control result into an out of control condition or into an in control condition, deleting or excluding a result, and so on, and updating information for display on all screens.

[0029] The rule evaluation module is the background module which is responsible for evaluating control results against the selected QC rules. This module keeps sufficient information about the most recent control results to be able to evaluate each control result against all selected rules as each control result is received. The rule evaluation module ~~passes this information to the run module where patient results are completely evaluated as soon as they are received~~ from the various laboratory instrument interfaces. Except when bracketing mode is enabled, the system continuously evaluates and releases patient results to the patient results data base.

[0030] The flow diagram illustrated in Fig. 13 illustrates validation of results obtained from a laboratory instrument through an appropriate interface. As each result is provided to the system of the invention, it is identified as either a control result or a patient result. If the result is identified as a control result, it is next determined whether the result is a process control result. If the result is identified as a process control result, it is tested against the selected statistical quality control rules. See Fig. 14. If the system and method are not operating in bracketing mode, results passing testing against the selected statistical quality control rules are supplied to the QC test status data base. If the system and method are operating in bracketing mode, and the end of the bracket has not yet been reached, the results are added to the long term quality control data base. If the system and method are operating in bracketing mode, and the end of the bracket has been reached, all patient results within the bracket are either blocked or released, depending upon whether the control results passed testing against the selected statistical quality control rules. All control results are added to the long term quality control data base. The system and method then return for evaluation of the next result. If the control result is not a process control result, it is added to the long term QC data base. If the result is a patient result, it is validated technically. See Fig. 15. Once validated technically, it is validated against the QC test status. See Fig. 16. The system and method then return for evaluation of the next result. Finally, if a result is neither a control result nor a patient result, an error is indicated.

[0031] In the application of the rules, Fig. 14, the decision is first reached whether more rules are selected or configured. If not, the system and method have finished testing the result against the selected rules. If so, the system and method get the next rule against which the result is to be tested. The system and method determine whether all results required by the rule to conduct the indicated test are available. If not, the status of the test is indicated as incomplete, and the system and method return to determine if all results required by the rule to conduct the indicated test are available. If so the system and method determine whether the rule has been violated by the result. If not, the process is indicated as being in control with respect to that particular rule, and the system and method return to test the result against the next rule. If the rule is determined to have been violated, the severity of the violation is ascertained. There are, as

noted above, two levels of severity, caution and out of control. If the process is adjudged out of control, an indication of the out of control status of the result with respect to that rule is produced, the status of the test with respect to that rule is stored in the QC test status data, and the system and method return to test the result against the next rule. If the process is adjudged to be in a caution condition, an indication of the caution status of the result with respect to that rule is produced, and the status of the QC test with respect to that rule is determined. If the QC test status is already in an out of control condition, the system and method return to test the result against the next rule. If the QC test status is not in an out of control condition, an indication of the caution status of the result with respect to that rule is produced, the status of the test with respect to that rule is stored in the QC test status data, and the system and method return to test the result against the next rule. It should be noted that the system and method will not reduce the severity of system status with respect to a selected rule, for example, change an indication of the system status with respect to a selected rule from red to yellow, red to green, or yellow to green. An operator must intervene to achieve this. However, the system and method will increase the severity of the system status with respect to a selected rule, for example, change it from green to red, green to yellow, or yellow to red, automatically whenever such action is warranted by the results of testing.

[0032] In quality control test status validation, Fig. 16, the system and method first determine if the QC test status is indicated as out of control. If so, a result is marked with a QC error and blocked. The result is saved to the data base and the QC test status validation is complete. If the QC test status is not indicated as being out of control, the timing of the result is ascertained. If the result is prior in time to the most recent determination, based upon testing of a control, that the process is in control, the result is blocked. Underlying this action is the assumption that the QC test must have indicated that the process being tested was out of control prior to the most recent event indicated to be in control. If the result is not prior in time to the most recent event indicated as being in control, the system and method next determine whether the result has been blocked. If so, the result is saved to the data base. If not, the system and method next determine whether bracketing is enabled. If so, the result's state is set to QC pending, pending testing of the bracket closing control's(s') result(s) against the selected rule(s). The result is then saved to the data base. If bracketing is not enabled, the result is released to be saved to the data base. Once the result is saved to the data base, QC test status validation is complete.

[0033] In technical validation, Fig. 15, the system and method first determine whether the result has been generated on a laboratory instrument already flagged for some reason. This might occur, for example, if the operator already is aware that the instrument is in need of service, etc. If the instrument has already been flagged, the result is marked "instrument flagged," and the result is blocked from passage to the data base. If the instrument is not flagged, the test is next validated against the normal ranges for the test. The best matching normal range for the test is identified, and the test is validated against that range. If no normal range for the test is identified, the result is so marked, and, depending on the setting of a file in the system, the result may be blocked. If a normal range for the test is identified, the result is marked, and, depending on the setting of a file in the system, the result may be blocked. After the test is validated against the normal range, or, where no normal range can be found, the result is marked as having no normal range, or where the test is not validated against a normal range, the test is next validated against prior results for the same patient. If there are no prior results in the patient data base for the patient, the result is so marked. If there are prior results in the data base for the patient, the percentage change is checked against the allowable change, the result is marked with that change, and, depending on the setting of a configuration file in the system, the result may be blocked. Once the result is marked with a percentage change, or, where no prior patient data exists, marked to indicate that such marking is not possible, or where the test is not validated against prior patient results, the technical validation is complete.

## Claims

1. A system for analyzing the results of determinations of the concentrations of medically significant components of control solutions, the system comprising a programmable machine and a program executable on the machine for testing the results against a set of multiple rules, and for producing indications to an operator of the results of the tests.
2. The system of claim 1 further comprising an instrument for sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions, and an interface for relaying the results of the determinations of the concentrations of the medically significant components of the control solutions to the programmable machine to be tested by the program.
3. The system of claim 2 wherein the program for testing the results against multiple rules comprises a program for testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules, and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second

sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.

- 5 4. The system of claim 2 wherein the instrument for sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions comprises an instrument for sequentially determining the concentrations of different medically significant components of samples of different body fluids and different control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and different control solutions, and the program comprises a program for instructing the instrument to determine the concentrations of different medically significant components of samples of different body fluids and different control solutions, the system further comprising an interface for relaying instructions from the programmable machine to the instrument.
- 10 5. The system of claim 4 wherein the program for testing the results against the set of multiple rules comprises a program for testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.
- 15 6. The system of claim 2 further comprising a second instrument for sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions, and an interface for relaying the results of determinations by the second instrument to the programmable machine to be tested by the program.
- 20 7. The system of claim 6 wherein the program for testing the results against multiple rules comprises a program for testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules, and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.
- 25 8. The system of claim 6 wherein the instrument and the second instrument respectively comprise: an instrument for ~~sequentially determining the concentrations of different medically significant components of samples of different~~ body fluids and control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and control solutions; and, a second instrument for sequentially determining the concentrations of different medically significant components of samples of different body fluids and control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and control solutions, and the program comprises a program for selectively instructing one of the instrument and the second instrument to determine the concentrations of different medically significant components of samples of different body fluids and control solutions, the system further comprising an interface for relaying instructions from the programmable machine to the one of the instrument and the second instrument.
- 30 9. The system of claim 8 wherein the program for testing the results against the set of multiple rules comprises a program for testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules and subsequently testing a result of at least one of a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.
- 35 10. A method for analyzing the results of determinations of the concentrations of medically significant components of control solutions, the method comprising the steps of providing a programmable machine, testing the results on the machine against a set of multiple rules, and producing indications to an operator of the results of the tests.
- 40 11. The method of claim 10 further comprising the step of sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions, and relaying the results of the determinations of the concentrations of the medically significant components of the control solutions to the programmable machine to be tested by the program.
- 45 50 55

12. The method of claim 11 wherein testing the results against multiple rules comprises testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.

13. The method of claim 11 wherein sequentially determining the concentrations of medically significant components of multiple samples of body fluids and control solutions comprises sequentially determining the concentrations of different medically significant components of samples of different body fluids and control solutions in response to instructions to determine the concentrations of different medically significant components of samples of different body fluids and control solutions, instructing the determination of the concentrations of different medically significant components of samples of different body fluids and control solutions, and relaying instructions from the programmable machine to the instrument.

14. The method of claim 13 wherein testing the results against the set of multiple rules comprises testing a result of a first determination of the concentration of a first medically significant component of a first sample of a first control solution against a first subset of the set of multiple rules and subsequently testing a result of at least one of: a second determination; the concentration of a second medically significant component; a second sample; and, a second control solution against at least one of the first subset and a second subset of the set of multiple rules.

Operator: rusuli

Laboratory Systems Manager

Date: 1/11/96 4:43:19 PM

Preparation

Orders

Validation

Statistics

Tools

Utilities

Results

Test Status

QC Results

Status

Test

Instr.

ALL

ALL

ALL

Status	Test	Instr.	QC Event Hst:	Event	Control ID	Date/Time
OK	CKMb	ES002	4	Violation: 1x3s WR Rule	PNIM	1/10/96 12:49 AM
"	"	ES001	0	Status Green: JONESMT	PPIM	1/10/96 12:47 AM
"	FT3	"	0	Violation: 2of3x2s WR AC Rule	PPIM	1/10/96 12:44 AM
①	FT3	ELEC1	0	Warning: 4x1s AR Rule	PPIM	1/10/96 12:29 AM
"	FT3	ELEC2	2	Status Green: JONESMT		1/9/96 11:54 PM
"	FT4	ES001	4	Status Red: RICKSDJ		1/9/96 11:10 PM
"	FT4	ELEC2	2			
"	T3	ES002	2			
"	"	ELEC1	2			
"	T4	ES002	2			
"	"	ELEC1	2			
○	"	ELEC2	0			
"	"	ES001	0			
"	TBK	ELEC1	2			
"	CEA	"	2			
"	CK-MB	"	0			
"	CA 125	ES001	0			
"	CA 15-3	"	2			

Reset r

Go Red

Go Green

Rules

Comment

Details

Help

Alarm

Print

LogOff

FIG. 1

Operator: rusuli

Laboratory Systems Manager

Date: 1/11/96 4:43:19 PM

Preparation

Orders

Validation

Statistics

Tools

Utilities

Results

Test Status

QC Results

Status

Test

Instr.

ALL

ALL

ALL

<input checked="" type="radio"/>	CKMb	ES002	4	<
"	"	ES001	0	<<
"	FT3	"	0	<
①	FT3	ELEC1	0	>
"	FT3	ELEC2	2	>>
"	FT4	ES001	4	>
"	FT4	ELEC2	2	>>
"	T3	ES002	2	>
"	"	ELEC1	2	>>
"	T4	ES002	2	>
"	"	ELEC1	2	>>
○	"	ELEC2	0	>
"	"	ES001	0	>>
"	TBK	ELEC1	2	>
"	CEA	"	2	>>
"	CK-MB	"	0	>
"	CA 125	ES001	0	>>
"	CA 15-3	"	2	>

Last control results:

Result -3s +3s Target SD Date/Time

PPIM 91.3 81.4 10.3 1/10/96 12:29 AM

PNIM 28.24 20.6 4.7 1/8/96 9:08 AM

Current rule status:

Within Run:

1x3s ○ AC

2x3x2s ⊗ Inc.

4x1s Inc.

Across Runs:

2x2s ○ AC

2x3x2s ⊗

4x1s ①

mxbar Inc. Inc.

Run length: 4

Across Systems:

Rks ○ AC

⊗ = Error

① = Warning

○ = OK

Inc. = Incomplete

AC = Across Controls

Reset r

Go Red

Go Green

Rules

Comment

Details

? Help

⏏

Print

Alarm

Log Off

FIG. 2

Operator: rusull

Laboratory Systems Manager

Date: 1/11/96 4:43:19 PM

Preparation

Statistics

Validation

Tools

Utilities

Results

Test Status

QC Results

Status

Test

Instr.

ALL

ALL

ALL

Status	Test	Instr.	Count	Event	Control ID	Date/Time
OK	CKMB	ES002	4	Violation: 1x3s WR Rule	PNIM	1/10/96 12:49 AM
"	"	ES001	0	Status Green: JONESMT	PPIM	1/10/96 12:47 AM
"	FT3	"	0	Violation: 2of3x2s WR AC Rule	PPIM	1/10/96 12:44 AM
!	FT3	ELEC1	0	Warning: 4x1s AR Rule	PPIM	1/10/96 12:29 AM
"	FT3	ELEC2	2	Status Green: JONESMT		1/9/96 11:54 PM
"	FT4	ES001	4	Status Red: RICKSDJ		1/9/96 11:10 PM
"	FT4	ELEC2	2			
"	T3	ES002	2			
"	"	ELEC1	2			
"	T4	ES002	2			
"	"	ELEC1	2			
"	"	ELEC2	0			
"	"	ES001	0			
"	TBK	ELEC1	2			
"	CEA	"	2			
"	CK-MB	"	0			
"	CA 125	ES001	0			
"	CA 15-3	"	2			

QC Event Hist

Event

- Violation: 1x3s WR Rule
- Status Green: JONESMT
- Violation: 2of3x2s WR AC Rule
- Warning: 4x1s AR Rule
- Status Green: JONESMT
- Status Red: RICKSDJ

Edit

Event Comment

1/10/96 10:22 PM JONESMT Recalibrated  
1/10/96 12:47 AM RICKSDJ Similar to the problem I had yesterday when the air-conditioning failed.

Reset r

Go Red

Go Green

Rules

Comment

Details

? Help

Log On

Alarm

Print

Log Off

FIG. 3

Operator: rusull

Laboratory Systems Manager

Date: 1/11/96 4:43:19 PM

Status	Test	Instr.	QC Event	Event	Control ID	Date/Time
ALL	ALL	ALL	ALL	ALL	ALL	ALL
⊗	CKMb	ES002	4	Violation: 1x3s WR Rule	PNIM	1/10/96 12:49 AM
"	"	ES001	0	Status Green: JONESMT	PNIM	1/10/96 12:47 AM
"	FT3	"	0	Violation: 2of3x2s WR ACRule	PPIM	1/10/96 12:44 AM
①	FT3	ELEC1	0	Warning: 4x1s AR Rule	PPIM	1/10/96 12:29 AM
"	FT3	ELEC2	2	Status Green: JONESMT	PPIM	1/9/96 11:54 PM
"	FT4	ES001	4	Status Red: RICKSDJ	PPIM	1/9/96 11:10 PM
"	FT4	ELEC2	2			
"	T3	ES002	2			
"	"	ELEC1	2			
"	T4	ES002	2			
"	"	ELEC1	2			
"	"	ELEC2	0			
○	"	ES001	0			
"	TBK	ELEC1	2			
"	CEA	"	2			
"	CK-MB	"	0			
"	CA 125	ES001	0			
"	CA 15-3	"	2			

Event Details:	Result	-3s	+3s	Target	SD	Date/Time
PPIM	91.3	█	█	81.4	10.3	1/10/96 12:29 AM
"	92.02	█	█	81.4	10.3	1/9/96 11:54 PM
"	91.03	█	█	81.4	10.3	1/9/96 7:54 AM
PNIM	20.04	█	█	20.6	4.7	1/8/96 9:08 AM

FIG. 4

Operator: rusuli

Laboratory Systems Manager

Date: 9/23/96 1:45:42 PM

Preparation

Users

Inventory

Test Protocol

QC Rules

Layout

Statistics

Tools

Utilities

More

Test

Instr.

ALL

ALL

ES002

ES001

"

ELEC1

ELEC2

ES001

ELEC2

ES002

ELEC1

ES002

ELEC1

ELEC2

ES002

ELEC1

"

"

ES002

"

ES001

Save

Run Length (N):

6

Bracketing:

☒

WITHIN RUN RULES

	Within Control	Across Controls
1x2s	<input type="radio"/>	
1xKs	<input type="radio"/>	<input type="radio"/>
RxKs	<input type="radio"/>	<input type="radio"/>
2x2s	<input type="radio"/>	<input type="radio"/>
2of3x2s	<input type="radio"/>	<input type="radio"/>
3x1s	<input type="radio"/>	<input type="radio"/>
4x1s	<input type="radio"/>	<input type="radio"/>
Mxbar	<input type="radio"/>	<input type="radio"/>
Mmono	<input type="radio"/>	<input type="radio"/>

ACROSS RUN RULES

	Within Control	Across Controls
2x2s	<input type="radio"/>	<input type="radio"/>
2of3x2s	<input type="radio"/>	<input type="radio"/>
3x1s	<input type="radio"/>	<input type="radio"/>
4x1s	<input type="radio"/>	<input type="radio"/>
Mxbar	<input type="radio"/>	<input type="radio"/>
Mmono	<input type="radio"/>	<input type="radio"/>

ACROSS SYSTEMS RULES (with N-1)

RxKs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Use as reference	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Help

Alarm

Print

Logout

FIG. 5

Operator: rusuli

Laboratory Systems Manager

Date: 11/21/96 5:18:13 p

Preparation

Users

Test Def.

Orders

Inventory

Calc. Tests

Validation

Test Protocol

Profiles

Statistics

Distribution

Tools

Utilities

Exp. Ranges

Ctrl. Def.

Archive

More

Control ID	Lot Number	Instrument	Test Name
ALL	ALL	ALL	ALL
LYPH01	102	ELEC1	CkMb
LYPH01	102	ELEC1	FT3
LYPH01	102	ELEC1	FT4
LYPH01	102	ELEC1	T3
LYPH01	102	ELEC1	T4
LYPH01	102	ELEC1	TBK
LYPH01	102	ELEC1	TROPO
LYPH01	102	ELEC1	TSH
LYPH01	102	ELEC2	CA125
LYPH01	102	ELEC2	CA15
LYPH01	102	ELEC2	CA19
LYPH01	102	ELEC2	CA72
LYPH01	102	ELEC2	CYFRA
LYPH01	102	ELEC2	FSH
LYPH01	102	ELEC2	FT3
LYPH01	102	ELEC2	FT4
LYPH01	102	ELEC2	HCG

Control ID

Lot Number

Instrument

Test Name

Control Sample ID

Item Long Name

QC Statistics

Manufacturer

View Unit

Control Type

LYPH01

102

ELEC1

CkMb

LYPH01\_ELEC1\_B

LYPH01

Precision

Boehringer

U/l

Process Control  
Study  
No Longer Used

Save

Keep

Transfer

Up

Down

Delete

Help

Alarm

Print

Logout

Operator: rusull

Laboratory Systems Manager

Date: 11/21/96 5:18:13 p

Preparation

Users

Test Def.

Orders

Inventory

Calc. Tests

Statistics

Validation

Test Protocol

Layout

Profiles

Exp. Ranges

Tools

Archive

Utilities

More

Ctrl. Def.			
Control ID	Lot Number	Instrument	Test Name
ALL	ALL	ALL	ALL
LYPH01	102	ELEC1	CkMb
LYPH01	102	ELEC1	FT3
LYPH01	102	ELEC1	FT4
LYPH01	102	ELEC1	T3
LYPH01	102	ELEC1	T4
LYPH01	102	ELEC1	TBK
LYPH01	102	ELEC1	TROPO
LYPH01	102	ELEC1	TSH
LYPH01	102	ELEC2	CA125
LYPH01	102	ELEC2	CA15
LYPH01	102	ELEC2	CA19
LYPH01	102	ELEC2	CA72
LYPH01	102	ELEC2	CYFRA
LYPH01	102	ELEC2	FSH
LYPH01	102	ELEC2	FT3
LYPH01	102	ELEC2	FT4
LYPH01	102	ELEC2	HCG
Delete			

Manufacturer's Target Value
Manufacturer's Deviation 1s
Precision Target Value
Precision Lower Range
Precision Upper Range
Precision Deviation 1s
Precision Deviation 2s
Current Mean
Current 1s

104.5251  
2.2501

Save

Keep

Transfer

Up

Down

Help

Alarm

Print

Logout

FIG. 7

Operator: WedelDL

Laboratory Systems Manager

Date: 9/20/96 1:44:24 PM

Preparation Test Status QC Results Validation Statistics Tools Utilities

Control Type: Process Control  
Control ID: PPIM  
Control Lot No: 101  
Test: algM  
Test Lot No: 28  
Last Operator: Bruns  
Validation Date: 1/18/95 10:36 PM

Precision Target Values  
Target Value: 90 mg/dl  
Range: 76.50 - 103.50  
Result Dev.: 3.04 %  
Result SDI: 0.64  
Result Date: 1/18/95 10:46 PM  
Entries in Statistic: 10  
Position in Run (n): 3

Test	Instr.	Control ID	QC-Value	Status	Flag
ALL	ALL	ALL	Result -3: +3	ALL	
algM	ES002	PPIM	92.74		Validate
"	"	"	85.57		"
"	"	"	91.24		"
"	"	"	92.77		"
"	"	"	97.61		"
"	"	"	89.74		"
"	"	"	98.08		"
"	"	"	86.07		"
"	"	"	86.3		X
"	"	"	83.53		"
"	"	PNIM	76.96		"
"	"	"	79.97		X
"	"	"	94.92		3s
"	"	"	79.62		Upload
"	"	"	81.53		"
"	"	"	91.92		Validate W1
"	"	"	84.74		Upload
"	"	"	79.81		"

Include Exclude Delete Comment

Help Alarm Print LogOff

FIG. 8

Operator: WedelDL

Laboratory Systems Manager

Date: 9/20/96 1:44:24 PM

Preparation

Orders

Validation

Statistics

Tools

Utilities

Results

Test Status

QC Results

Pat. Name	Patient ID	Sample ID	Test	Result	Status	Last Operator	Result Date/Time	Requestor	Instrument	Unit	Pat. Name	Patient ID	Sample ID	Status
ALL	ALL	ALL	ALL	ALL	ALL	Neubert	1/10/95 6:27 PM	Dr. Mues	ELEC1	pg/ml			LYPH01_ELEC1_	User (at LSM) App
FERNHOLZ, 10004	"	24980	CA125	11.52	DA									
"	"	"	PSA	0.93	DA									
LIN, Helga 9995	"	24978	CKMb	17.24	HI, DA									
"	"	"	TROPO	1.55	DA									
"	"	"	PSA	0.27	HI									
"	"	"	CA125	11.74	DA									
"	"	24976	TSH	1.59	DA									
		LYPH01_1	FT3	9.78	"									
		LYPH02_1	"	0.75	"									
		LYPH03_1	"	0.86	"									
LIN, Helga 9995	"	24976	"	17.18	HI, DA									
"	"	"	T3	1.7	DA									
		LYPH01_1	FT4	109.27	"									
		LYPH02_1	"	112.53	"									
		LYPH03_1	"	111.59	"									
LIN, Helga 9995	"	24976	"		DAP									
"	"	"	T4	21.71	HI, DA									
			All		All									

Comment

Add Test

Re-run

Release

Block

Document

More

Tech. Det.

?

Help

Alarm

Print

Log Off

FIG. 9

Operator: WedelDL

Laboratory Systems Manager

Date: 9/20/96 1:44:24 PM

Preparation

Orders

Validation

Statistics

Tools

Utilities

Results

Test Status

QC Results

Pat. Name	Patient ID	Sample ID	Test	Result	Status
ALL	ALL	ALL	ALL	ALL	ALL
FERNHOLZ, 10004	"	24980	CA72	0.83	DA
"	"	"	PSA	0	DA
"	"	"	CA125	11.52	DA
LIN, Helga 9995	"	24978	CKMb	17.34	HI, DA
"	"	"	TROPO	0.55	DA
"	"	"	APSA	6.27	HI
"	"	"	CA125	34.74	DA
"	"	24976	TSH	1.59	DA
"	"	LYPH01_1	FT3	76.70	"
"	"	LYPH02_1	"	88.75	"
"	"	LYPH03_1	"	97.86	"
LIN, Helga 9995	"	24976	"	17.10	HI, DA
"	"	"	T3	1.7	DA
"	"	LYPH01_1	FT4	108.27	"
"	"	LYPH02_1	"	128.53	"
"	"	LYPH03_1	"	131.89	"
LIN, Helga 9995	"	24976	"	1	DA, P
"	"	"	BT4	27.7	HI, DA
"	"	"	"	"	All

Delete

More

Ech. Del.

Last Operator: Neubert

Result Date/Time: 1/10/95 6:27 PM

Requestor: Dr. Mues

Instrument: ELEC1

Unit: pg/ml

Pat. Name:

Patient ID:

Sample ID: LYPH01\_ELEC1\_

Status: User (at LSM) App

?

Help

Print

Alarm

LogOff

FIG. 10

Operator: rusuli

Laboratory Systems Manager

Date: 11/22/96 9:17:33 AM

Preparation

Orders

Validation

Statistics

Utilities

Users

Inventory

Test Protocol

Distribution

More

Time Settings

Archive Rules

Comment Def.

Lab. Mgmt.

Label

Recallibrated

Instrument was recalibrated

Comment

Instrument was recalibrated

Label

Recallibrated

Instrument was recalibrated

Comment

Instrument was recalibrated

Label

Bad material

Bad material was used for result

Comment

Bad material was used for result

Save

Delete

?

Help

Log Off

Print

Alarm

FIG. 11

Operator: rusuli      Laboratory Systems Manager      Date: 11/22/96 9:17:33 AM

Preparation	Orders	Validation	Statistics	Tools	Utilities
Users	Inventory	Test Protocol	Distribution	Lab. Mgmt.	More

Names	Access Rights	Requestors	Screen
Supervisor	NoAccess	▼	ALL
Operator	NoAccess	▼	Preparation Overview
Service	NoAccess	▼	Instrument Inventory

Worklist

Order Test

Demographics

Results

QC Results

Test Status

Basic QC

LogViewer

Lab Overview

Utilities Standard Comments

Utilities User Access Rights

QC Rules Configuration

Utilities User

Save

?	Help	Print	Alarm	LogOff
---	------	-------	-------	--------

FIG. 12

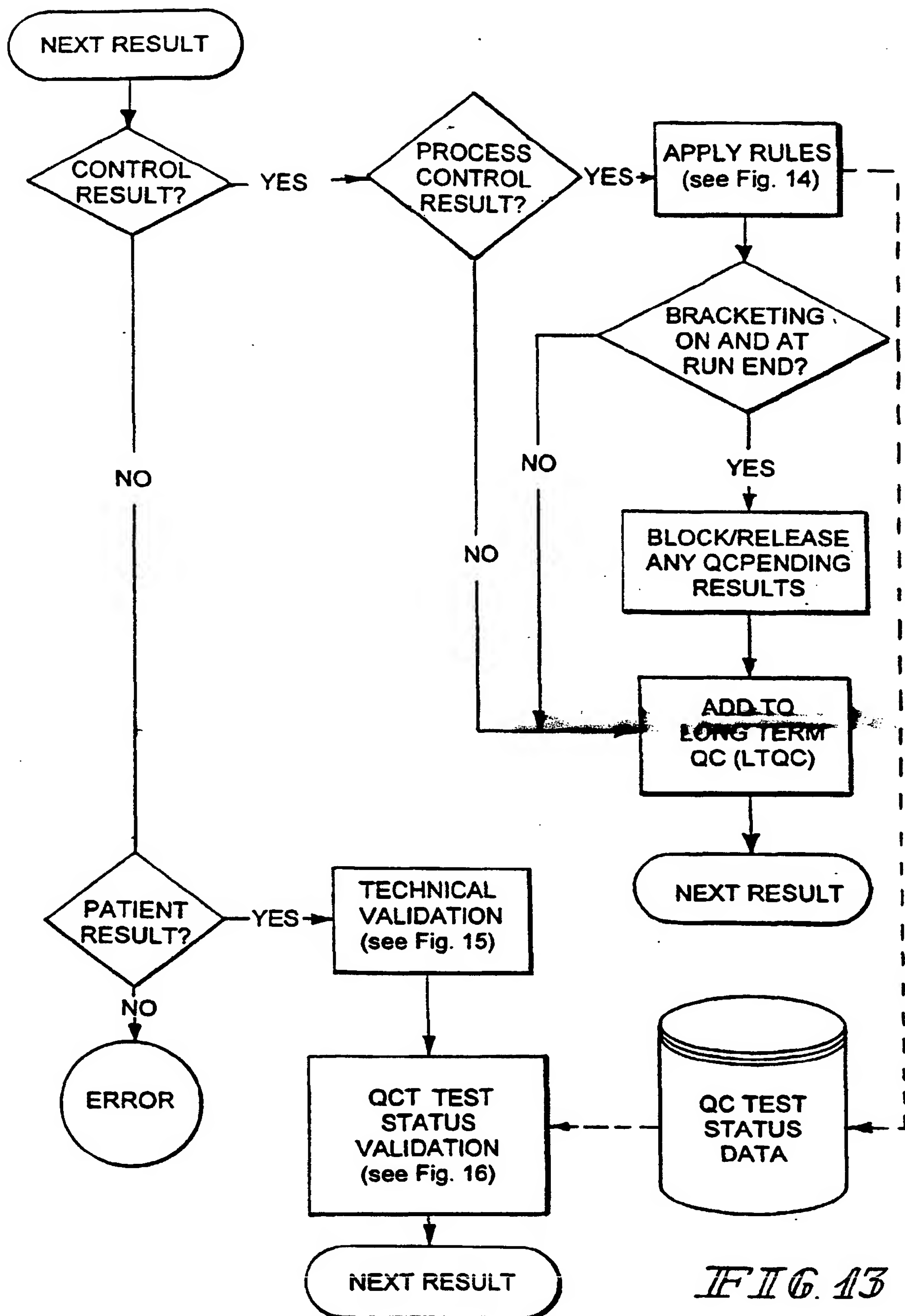
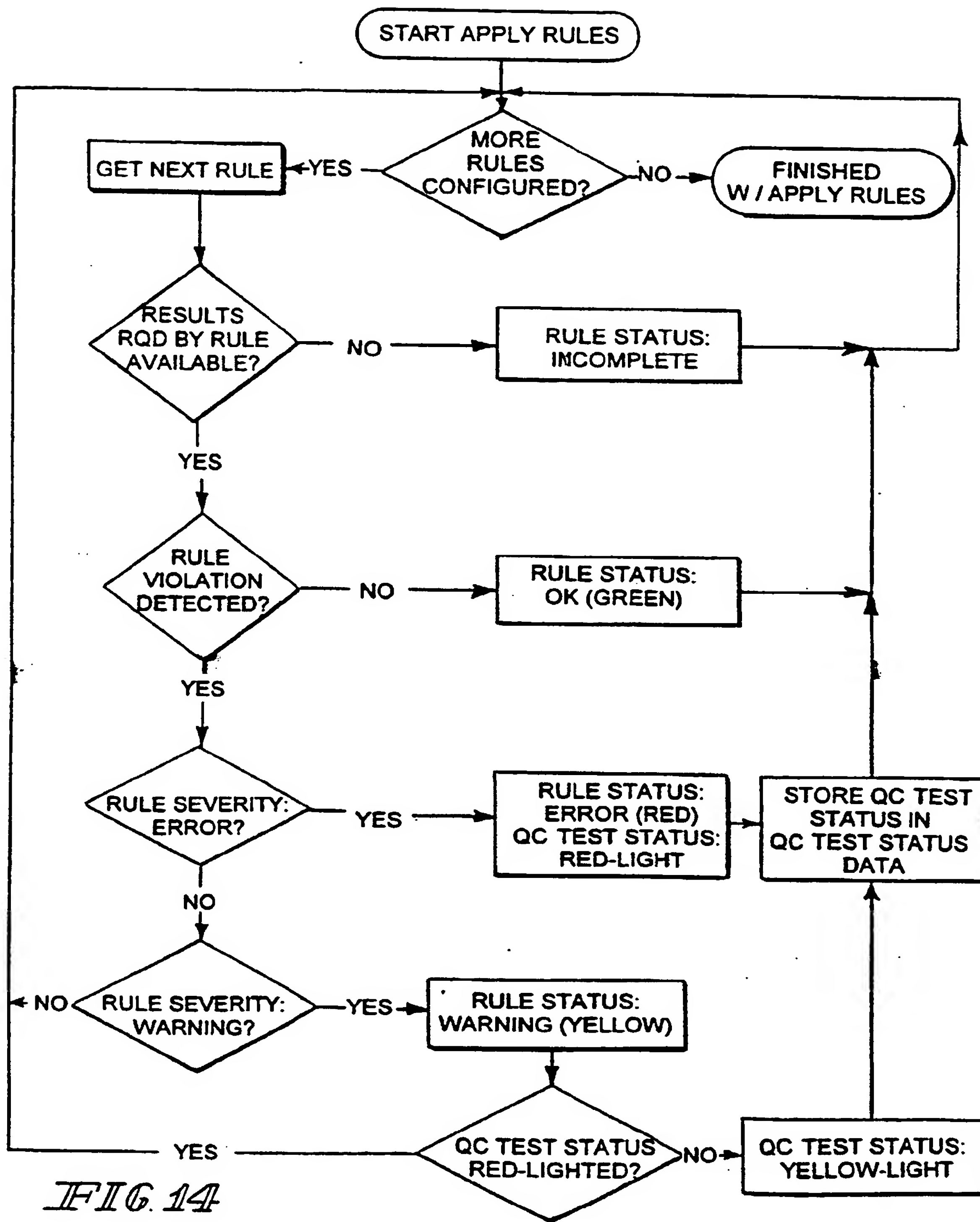
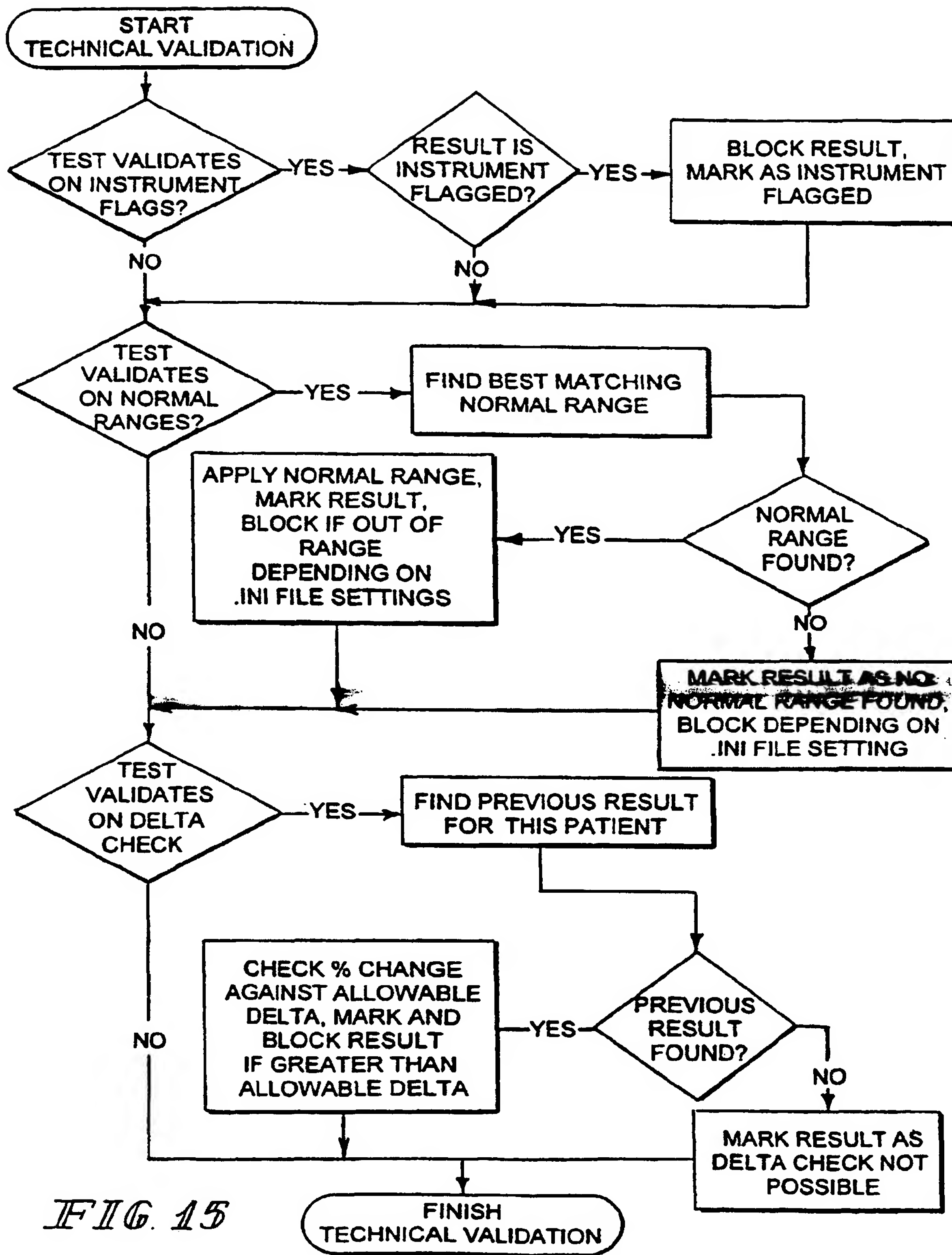


FIG. 13





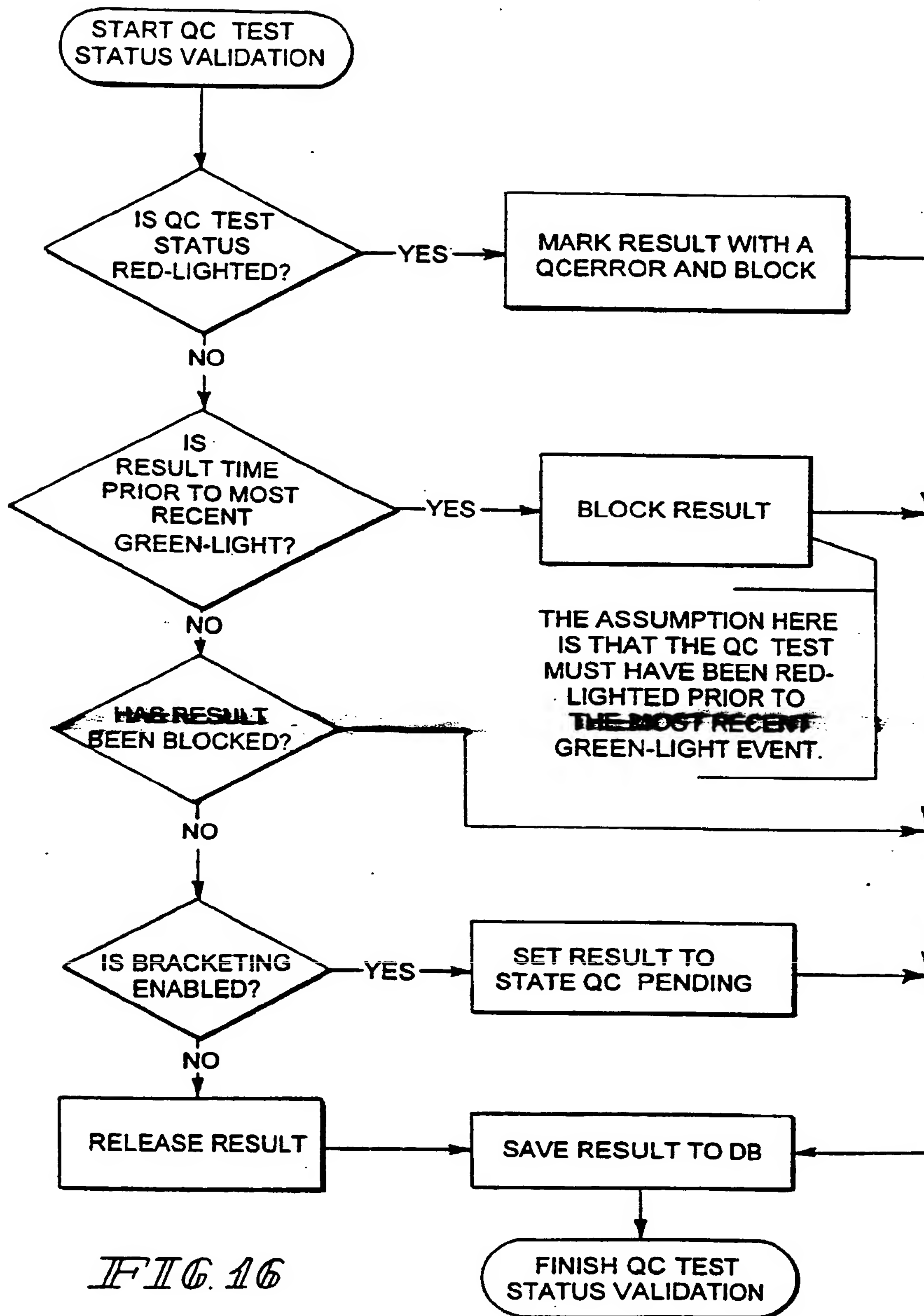


FIG. 16

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(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



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EP 0 962 872 A3

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### ~~(57)~~ Multi-rule quality control method and apparatus

(57) A method and apparatus for analyzing the results of determinations of the concentrations of medically significant components of control solutions comprise providing a programmable machine, executing on the machine a program which tests the results against a set of statistical quality control rules, and producing indications to an operator of the results of the tests. Illustratively, (a) laboratory analytical instrument(s) run(s) the control solutions interspersed among patient samples, the concentrations of medically significant components of which are determined by the laboratory instrument(s). The quality of the laboratory instrument(s) process(es) for determining the concentrations of the medically significant components of the patient samples are monitored by testing the outcomes of the concentration determinations of the control solutions against the set of QC rules. The QC testing process is conducted as the concentrations of the medically significant components of the control solutions are determined, so that delays between the determination of the concentrations of the medically significant components of the patient samples and the determination of the state of control of the process(es) by which those concentrations are determined are minimized.

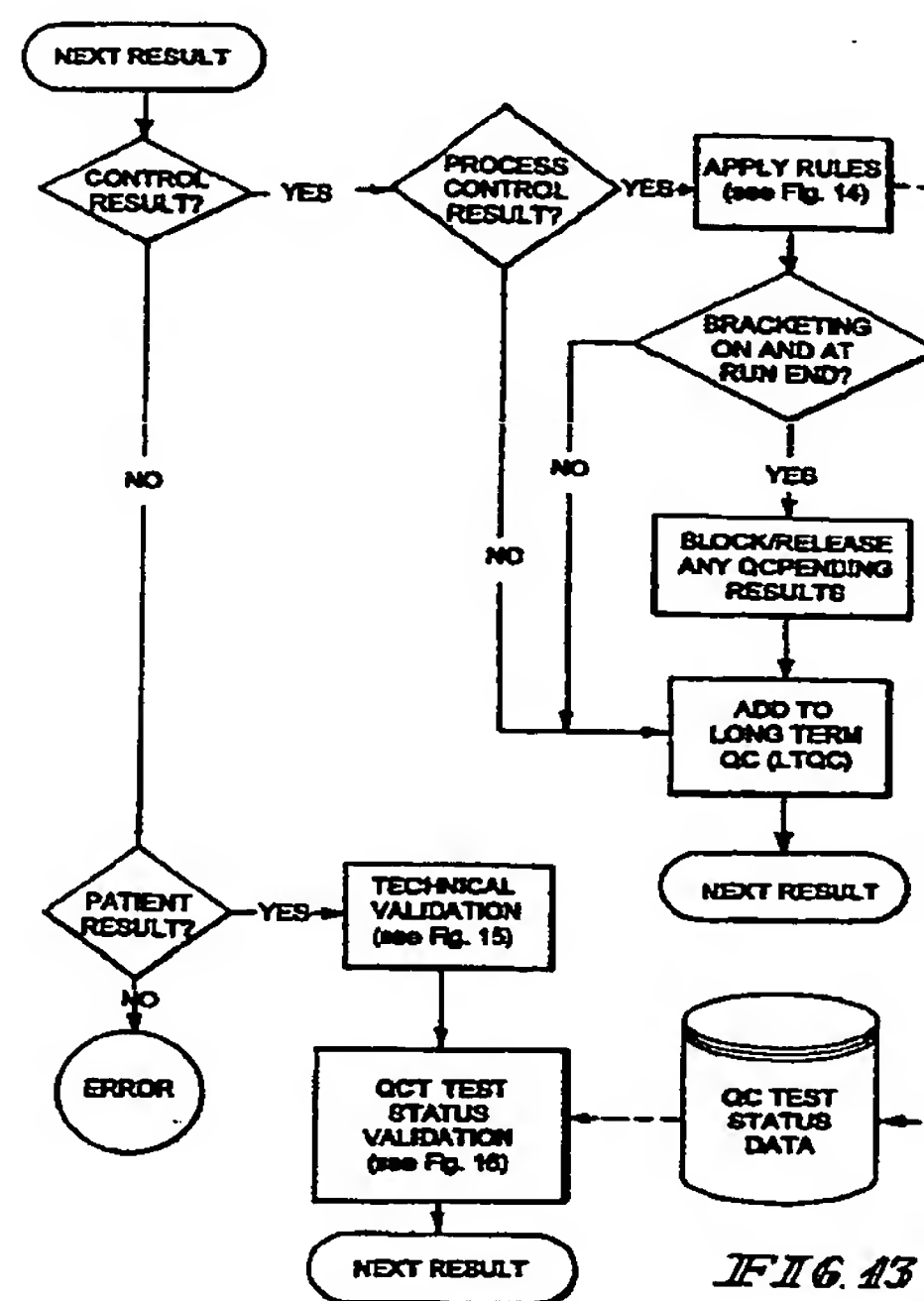


FIG. 13

EP 0 962 872 A3



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# EUROPEAN SEARCH REPORT

Application Number  
EP 99 10 5107

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The present search report has been drawn up for all claims			
Place of search <b>MUNICH</b>		Date of completion of the search <b>5 October 1999</b>	Examiner <b>Barba, M</b>
<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons * : member of the same patent family, corresponding document</p>			

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<p><b>CATEGORY OF CITED DOCUMENTS</b></p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			

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